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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,104	05/16/2001	Sanford H. Barsky	30435.73USWO	3615

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EXAMINER

FALK, ANNE MARIE

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 03/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/856,104

Applicant(s)

BARSKY ET AL.

Examiner

Anne-Marie Falk, Ph.D.

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12,28,29 and 50-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12,28,29 and 50-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The amendment filed December 9, 2004 has been entered. Claims 1, 5, 6, 9, 10, 11, and 28 have been amended.

Accordingly, Claims 1-12, 28, 29, and 50-52 remain pending in the instant application.

Applicants have not filed a statement of the substance of the interview conducted on December 3, 2004.

The rejection of Claims 1-5 under 35 U.S.C. 101 is withdrawn in view of the amendments to the claims to add the term "isolated."

The rejection of Claims 1-12, 28, 29, and 50-52 under 35 U.S.C. 102(a) is withdrawn in view of the Declaration of Dr. Sanford H. Barsky, dated December 9, 2004.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

Claims 5-9, 12, and 50-52 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for (i) a human inflammatory breast cancer (IBC) xenograft, wherein the xenograft grows within lymphatic and blood vessel channels of an immunocompromised mouse, (ii) a mouse model for IBC comprising an immunocompromised mouse which itself comprises a human inflammatory breast cancer xenograft, wherein the xenograft is present within lymphatic and blood vessel channels and has the claim-designated properties (see Claim 10), (iii) an *in vitro* culture of a human IBC

Art Unit: 1632

cell line, wherein the cell line grows as a spheroid and has the claim-designated properties (see Claim 6), (iv) a method of generating the xenograft set forth in part (i) by implanting appropriate cells into an immunocompromised mouse, and (v) a method of identifying a molecule whose expression is modulated in IBC, wherein the method involves using a human IBC xenograft that grows within lymphatic and blood vessel channels of an immunocompromised mouse, does not reasonably provide enablement for the use of an immunocompromised host animal other than a mouse in generating the claimed animal model or propagating the claimed xenograft. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims reciting "xenograft" without including a limitation reciting passage through a mouse cover material passaged through other animals and therefore are still subject to the enablement rejection. Claims 5, 12, and 50-52 recite specific ATCC accession numbers, but the claim language appears to cover human IBC cells passaged through animals other than mice, as well as cells that have not been passaged through an animal. In the interview of December 3, 2004, the Attorney agreed to point to the relevant sections of the specification that clarify whether the material on deposit and mentioned in the claims is material that has actually been passaged through an animal or is the original cell line prior to passage through an animal. See the Examiner Interview Summary mailed 12/8/04. In the interview, the Attorney stated that the human IBC cells had been passaged through an animal. However, the Examiner does not see where the specification provides this information.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1632

Claim 9 stands rejected and Claims 9-12 and 51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 stands rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: a selection step for identifying and obtaining IBC cells that exhibit the expression profile recited in Claim 1.

Claim 9 is indefinite in its recitation of “the immunocompromised host” in step (d) because the phrase lacks antecedent basis.

Claim 10 is indefinite in its use of the term “murine” and “mouse” in the same claim. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by “such as” and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, Claim 10 recites the broad recitation murine, and the claim also recites mouse which is the narrower statement of the limitation. The term “murine” covers rat and mouse, but the specification does not teach a rat model. Claims 11 and 12 are indefinite insofar as they depend from Claim 10.

Art Unit: 1632

Claims 11 and 12 are indefinite in their recitation of "[t]he animal model" because the phrase lacks antecedent basis.

Claim 51 is indefinite in its recitation of "[t]he nonhuman animal model" because the phrase lacks antecedent basis.

Conclusion

Claims 1-4 are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Art Unit: 1632

Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (571) 272-0728. The examiner can normally be reached Monday through Friday from 10:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735. The central official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Anne-Marie Falk, Ph.D.

Anne-Marie Falk
ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER